Peripheral Inventions

Mechanical Trauma as a Cause of Late Complications

after AneuRx® Stent Graft Repair of Abdominal Aortic Aneurysms

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We present a series of 4 patients in whom mechanical trauma was identified as a factor in the development of late complications after AneuRx® Stent Graft placement for repair of abdominal aortic aneurysms.

In all 4 patients, Type I or III endoleaks (and pseudoaneurysms in 2 patients) were discovered several months after abdominal aortic aneurysm repair with the AneuRx device. Two patients had sustained blunt abdominal trauma in a car accident, one had suffered a traumatic fall, and another had been participating in vigorous rowing activity. In all patients, the trauma had occurred several months before the diagnosis of endoleak or pseudoaneurysm (or both) was established. In all patients, follow-up computed tomographic scans identified the complications.

In conclusion, blunt mechanical injury is an unrecognized factor contributing to the late failure of endovascular stent grafts. Vigorous physical activity may also contribute to graft disruption or to the separation of modular components. ***(Tex Heart Inst J 2003; 30:186-93)***

Key words: *Aortic aneurysm, abdominal; aortic rupture; blood vessel prosthesis implantation; endovascular repair; iliac aneurysm; postoperative complications; prosthesis failure; stents; trauma*

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Endovascular exclusion of abdominal aortic aneurysms has gained widespread acceptance in the cardiovascular community, and more such cases are now being treated by this method than ever before. The feasibility and short-term benefits are no longer in doubt; however, long-term outcomes for the 1st generation of commercially available devices are not yet available. According to multicenter clinical trial data[1] on the AneuRx® AAA Stent Graft (Medtronic AVE, Inc.; Sunnyvale, Calif), late endoleaks occur in 6% to 9% of patients over a mean follow-up period of 2 years (Table I). The EUROSTAR experience[2] showed a clear relation between endoleaks and aneurysmal rupture, and also demonstrated that aortic remodeling that leads to graft kinking also increases the risk of rupture.

Reports of late abdominal aortic aneurysm (AAA) rupture after "successful" endograft repair of AAA have raised concern over the long-term success of this procedure.[3] The exact causes of this delayed failure are still speculative.

We describe the cases of 4 patients in whom endograft failure was related (at least in part) to mechanical trauma.

Case Reports

Patient 1

A 78-year-old obese man with a history of advanced chronic obstructive pulmonary disease, a mechanical aortic valve (necessitating warfarin use), and severe coronary artery disease with ischemic cardiomyopathy (requiring chronic oxygen therapy) was found to have an 8.5-cm infrarenal AAA. In view of the severe comorbidities, we recommended endovascular repair with an AneuRx device. A diagnostic abdominal aortogram revealed bilateral iliac artery stenosis with severe calcification and tortuosity of the iliac arteries (Fig. 1A). The patient underwent bilateral iliac angioplasty and WALLSTENT® (Boston Scientific Corporation; Natick, Mass) placement in order to facilitate the AAA repair with the AneuRx device. Three weeks after the iliac intervention, he underwent successful exclusion of the AAA with a 26-mm-wide, 165-mm-long bifurcated AneuRx device with a 15-mm-wide, 115-mm-long contralateral limb, which was placed in the right iliac ar-

tery (Fig. 1B). There was no endoleak or any complication at the end of the procedure.

Ten days after the procedure, while driving, the patient was involved in a traffic accident. The patient suffered blunt seat belt trauma to the abdomen with bruising but no apparent bone injury. He experienced some lower abdominal pain, which gradually resolved. He stated, however, that when lifting heavy objects, he still had some abdominal discomfort. A routine follow-up computed tomographic (CT) scan 6 months after the accident revealed the presence of an endoleak that originated 30 mm from the distal end of the right iliac limb (Figs. 2A and 2B). An angiogram confirmed the CT findings. At the same site, there was a pseudoaneurysm associated with the endoleak (Fig. 3). We attempted to repair the endoleak percutaneously by placing a 14-mm-wide, 55-mm-long AneuRx cuff, which was introduced through a 16F sheath (Cook, Inc.; Bloomington, Ind) via the right femoral artery. The cuff was deployed in the usual manner; however, due to the small caliber of the iliac artery and incomplete expansion of the cuff within the AneuRx iliac limb, there was resistance during retraction of the delivery catheter components. Despite repeated attempts to withdraw the nose cone of

TABLE I. Classification of Perigraft Flow or Endoleak*

Type	Description
Type I	Proximal or distal perigraft leak related to poor attachment seal
Type II	Collateral back flow, usually related to patent inferior mesenteric or lumbar arteries, into the aneurysmal sack
Type III	Fabric tear, poor seal, or modular disconnection
Type IV	Graft-wall porosity

*Defined as flow outside the graft lumen but contained within the aneurysm: the most common complication of stent-graft repair

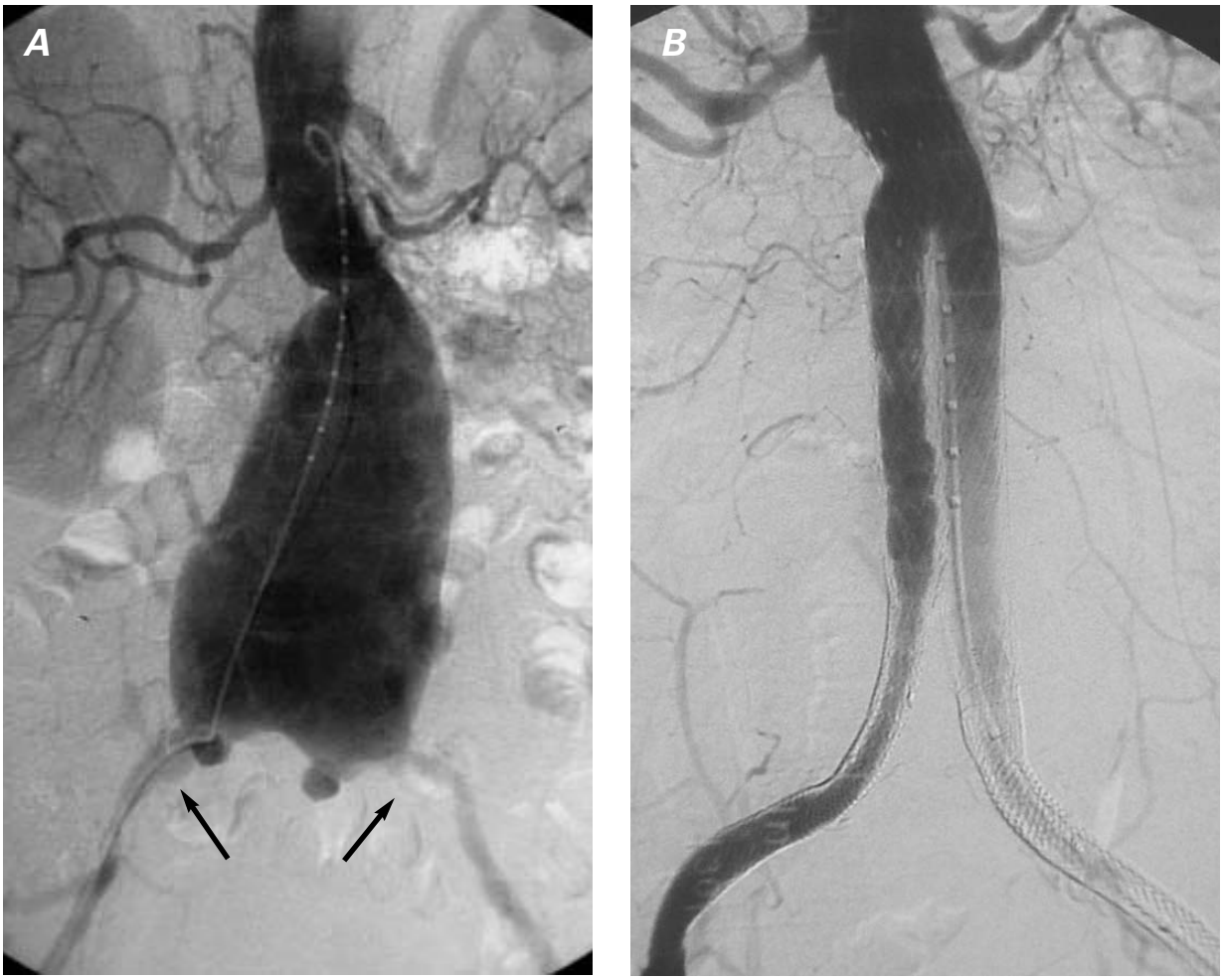

Fig. 1 *Patient 1.* ***A****) Abdominal angiogram before AAA exclusion, revealing very tortuous and narrow iliac arteries (arrows).* ***B****) Abdominal angiogram after successful deployment of the AneuRx stent graft*

the delivery catheter, it could not be retrieved. We also tried to pass a glide wire to perform right iliac limb angioplasty in an effort to free the delivery catheter. However, all attempts failed, and the patient underwent an open surgical repair of the AAA with removal of the entire stent graft. Surgical exploration confirmed the presence of a pseudoaneurysm that had formed at the origin of the right iliac artery. Close inspection of the stent graft revealed suture breakage and partial ring separation from the Dacron material as the cause of a Type III endoleak. The patient recovered uneventfully from the operation.

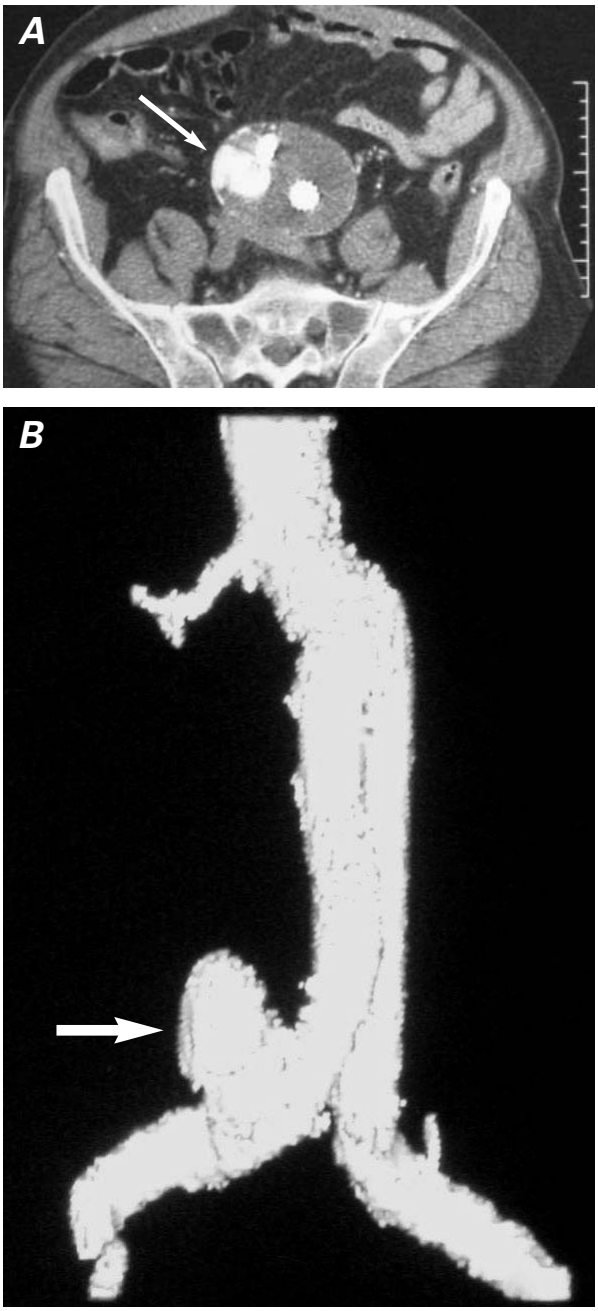

Fig. 2 *Patient 1.* ***A****) Computed tomographic (CT) scan, obtained 3 months after AAA repair with AneuRx stent graft, shows endoleak at the distal end of the right iliac limb (arrow).* ***B****) Three-dimensional CT reconstruction image shows an endoleak in the right iliac limb (arrow).*

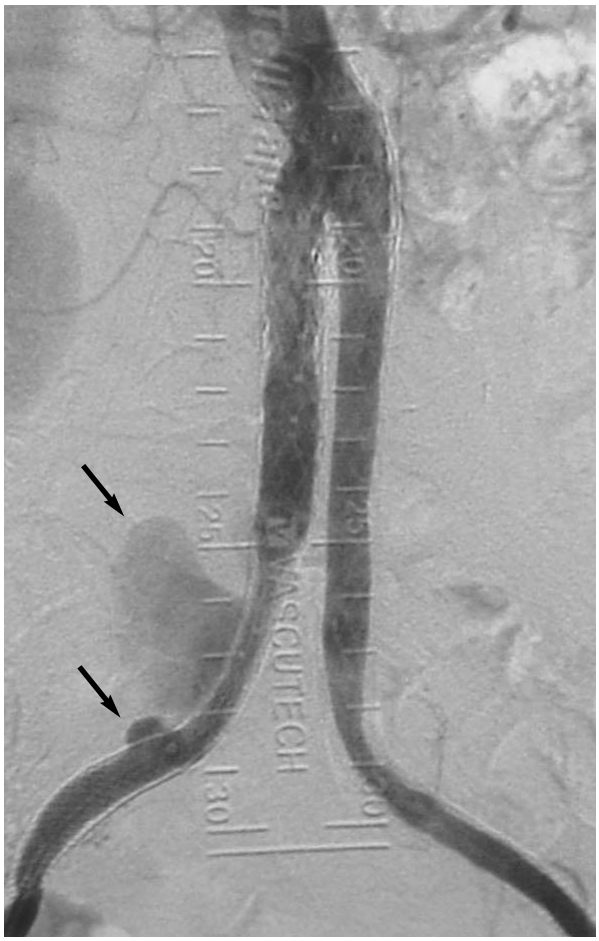

Fig. 3 *Patient 1. Abdominal angiogram shows an endoleak in the right iliac limb and a large pseudoaneurysm on the right side (arrows).*

Patient 2

A 72-year-old man was found to have a 5.5-cm infrarenal AAA. He had several comorbidities, including a prior stroke with substantial residual paralysis and sclerosing cholangitis, and was considered a high risk for conventional AAA repair. Therefore, he underwent an endovascular exclusion procedure with use of a 165-mm-long bifurcated AneuRx device that had a 24-mm aortic diameter and a 14-mm iliac diameter. A 14-mm-wide, 115-mm-long contralateral limb was used in the left iliac artery. The implantation was uneventful, and there was no endoleak at the end of the procedure (Fig. 4A). The patient remained asymptomatic, and follow-up CT scans at 6 months and 1 year did not show any endoleak or increase in the aneurysmal diameter.

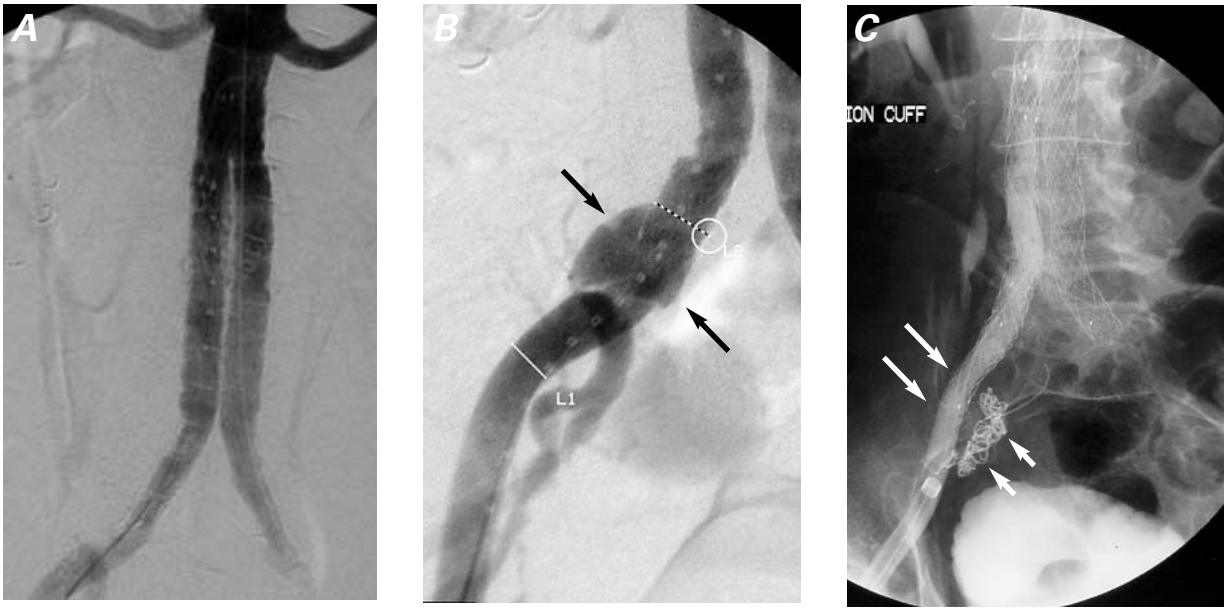

Fig. 4 *Patient 2.* ***A****) Abdominal angiogram after deployment of the AneuRx stent graft shows no endoleak.* ***B****) Follow-up angiography, performed 2 years after endoluminal repair of an AAA with the AneuRx stent graft, shows a pseudoaneurysm in the right common iliac artery at the distal end of the stent graft (arrows).* ***C****) Right iliac artery angiogram reveals successful endoluminal repair of right iliac artery pseudoaneurysm after coil embolization of the right internal iliac artery (small arrows) and placement of a 85-mm-long, 14-mm-wide AneuRx iliac limb (large arrows).*

Approximately 18 months after the procedure, the patient experienced syncope, fell from a significant height, and was found unconscious in a prone position with multiple bruises to his right flank and right groin area. He suffered no broken bones but did have a subdural hematoma that resolved with conservative treatment. He experienced some right-sided abdominal pain. The examination at that time with ultrasonography and noncontrast CT scanning revealed gallstones but no abdominal injury. After discharge from the hospital, the patient continued to have right-sided abdominal pain and underwent a cholecystectomy with only partial relief of the right-sided abdominal discomfort. A CT scan, obtained about 6 months after the accidental fall (and about 2 years after the AAA repair), revealed an endoleak that originated at the right common iliac artery. An iliac angiogram confirmed the presence of a Type I endoleak and the development of a pseudoaneurysm arising from the distal end of the right iliac limb of the graft (Fig. 4B). Percutaneous treatment of the endoleak was initiated immediately. First, the right internal iliac artery was obstructed by coil embolization through a right femoral artery approach to prevent retrograde filling of the right common iliac artery aneurysm. Then the pseudoaneurysm and the endoleak were successfully excluded with the deployment of an 85-mm-long, 14-mm-wide AneuRx iliac limb. The limb was placed so that it overlapped with the previously placed AneuRx limb by 20 mm and extended 20 mm beyond the origin of the occluded right internal iliac artery (Fig. 4C). Follow-up scans to date have shown no endoleak or aneurysm growth.

Patient 3

This case has been reported previously[3] as part of a series of late rupture cases, and is presented again here because the potential role of prior trauma in the causation of the rupture was not emphasized in the earlier report.

The patient was an 87-year-old man with coronary artery disease, congestive heart failure, prior stroke, and hypertension. He had an 8.5-cm infrarenal AAA that had been found 2 years earlier. The patient was seen at our institution for consideration of endoluminal repair of the AAA. Because we did not have an appropriately sized endograft, we referred the patient elsewhere for endoluminal repair. The aneurysm was repaired with a 165-mm-long AneuRx bifurcated stent graft. The aortic diameter of the graft was 28 mm, with 16-mm-wide, 115-mm-long iliac and contralateral iliac limbs. A Symphony® Stent (Boston Scientific Corp.) was deployed at the distal left iliac artery to seal a dissection. There were no endoleaks at the end of the procedure. The patient was then seen at our institution, and follow-up CT scanning performed 6 and 12 months after the procedure showed a decrease in aneurysm size to 6.5 cm and no endoleaks.

Twenty months after the procedure, the patient sustained blunt abdominal trauma during a motor vehicle accident. At 23 months, the patient presented elsewhere with abdominal and back pain. A CT scan demonstrated an increase in the size of the aneurysm and a large retroperitoneal hematoma. Plain abdominal radiographs showed a sharp angulation of the graft at the modular junction, migration of the left iliac limb from the main body of the graft, and a Type III endoleak. Emergent open surgery at another institution confirmed the radiologic findings and showed that the bifurcated graft and the right iliac limb had become disengaged at the modular junction. The patient died 10 days after surgery, secondary to multiple-organ failure.

Patient 4

This case of late graft failure has been reported by our group previously[4] and is being presented again here to emphasize the likely role of external mechanical insults in endovascular graft disruption.

A 58-year-old morbidly obese man underwent exclusion of a 7.8-cm infrarenal AAA with the use of a 165-mm-long AneuRx bifurcated stent graft; the aortic diameter of the device was 26 mm and the iliac diameter was 15 mm (Figs. 5A and 5B). The contralateral limb was 115 mm long and 15 mm wide. Due to distal device movement during retraction of the runners, an aortic extension cuff (26-mm wide by 375-mm long) was placed proximally, overlapping 1.5 cm with the main body of the bifurcated graft. There was no endoleak at the end of the procedure.

At 1-, 6-, and 12-month follow-up visits, the patient underwent CT scans that showed a patent stent graft, without evidence of migration or endoleak. However, at 6 and 12 months, the scans revealed an increase in angulation between the main graft body and the infrarenal neck. At the 2-year follow-up visit, a contrast-enhanced CT scan showed that the angulation had increased further. In addition, there was a Type III endoleak between the extension cuff and the main graft body, and the aneurysm had increased in size (Fig. 5C). Fluoroscopy revealed that the extension cuff was separated from the upper portion of the main graft body, which was severely deformed. Of note, this previously sedentary man had taken up active exercise on a rowing machine as a daily form of exercise.

The patient underwent an open surgical procedure, and the device was explanted successfully. Inspection of the stent graft at the time of surgery revealed separation of the aortic cuff from the main body of the bifurcated stent graft and breakage of the sutures at the most angulated part of the bifurcated endograft (Fig. 5D). He had a prolonged recovery related to respiratory and abdominal wound complications.

Discussion

The short-term results of endovascular AAA repair have been very encouraging. However, the relative paucity of long-term data, along with recent reports of late device failure and AAA rupture,[2-4,6,7] continues to generate concern and caution regarding the safety and long-term outcomes of this procedure.

Late Device Failure Mechanisms

Some of the mechanisms that have been implicated in late device failure include late endoleaks[1] and intrinsic stresses on the implanted graft secondary to aneurysmal shrinkage and remodeling.[5] Unfortunately, the absence of an endoleak does not always ensure the long-term success of the procedure.[6,7] Trauma as a contributing factor to late graft failure has not been studied in any detail, although it appears logical that any substantial extraneous mechanical force could damage a well functioning endograft. In reviewing these 4 cases, we have tried to highlight earlier mechanical trauma as a factor in late graft failure (Table II).

Patients 1 and 2 both presented with pseudoaneurysms and endoleaks several months after device implantation that was considered successful. Patient 1 presented with Type III endoleak and Patient 2 with Type 1 (Table II). It should be noted that pseudoaneurysms of iliac arteries after stent or stent graft placement are quite rare. There are few case reports of such pseudoaneurysms occurring after trauma. Both patients in the present report had sustained blunt injuries to the abdomen. Clearly, a sudden and forceful external impact could create a shear force at the site of transition from a native artery to a stent graft (due to the markedly different mechanical properties between the arterial wall segment and the stent graft at that point). Even a small tear could progress over time, resulting in an endoleak, a pseudoaneurysm, or both. In Patient 1, this was further promoted by severe right iliac artery stenosis and angulation that placed undue stress on the stent graft components. These conditions caused breakage of the sutures, producing the defect in the graft material and the Type III endoleak. The separation of the stent ring from the graft material freed sharp edges of the nitinol rings, which in turn caused perforation of the right common iliac artery and formation of pseudoaneurysms.

Patients 3 and 4 both had late Type III endoleaks with separation of the main bifurcated graft at the modular junction (from the contralateral iliac limb in Patient 3 and from the proximal aortic extension cuff in Patient 4) (Table II). In both patients, radiographs showed anterior displacement of the stent graft with increased angulation at the modular junction.

Aneurysmal shrinkage and aortic remodeling has been shown to result in anterior and lateral displace-

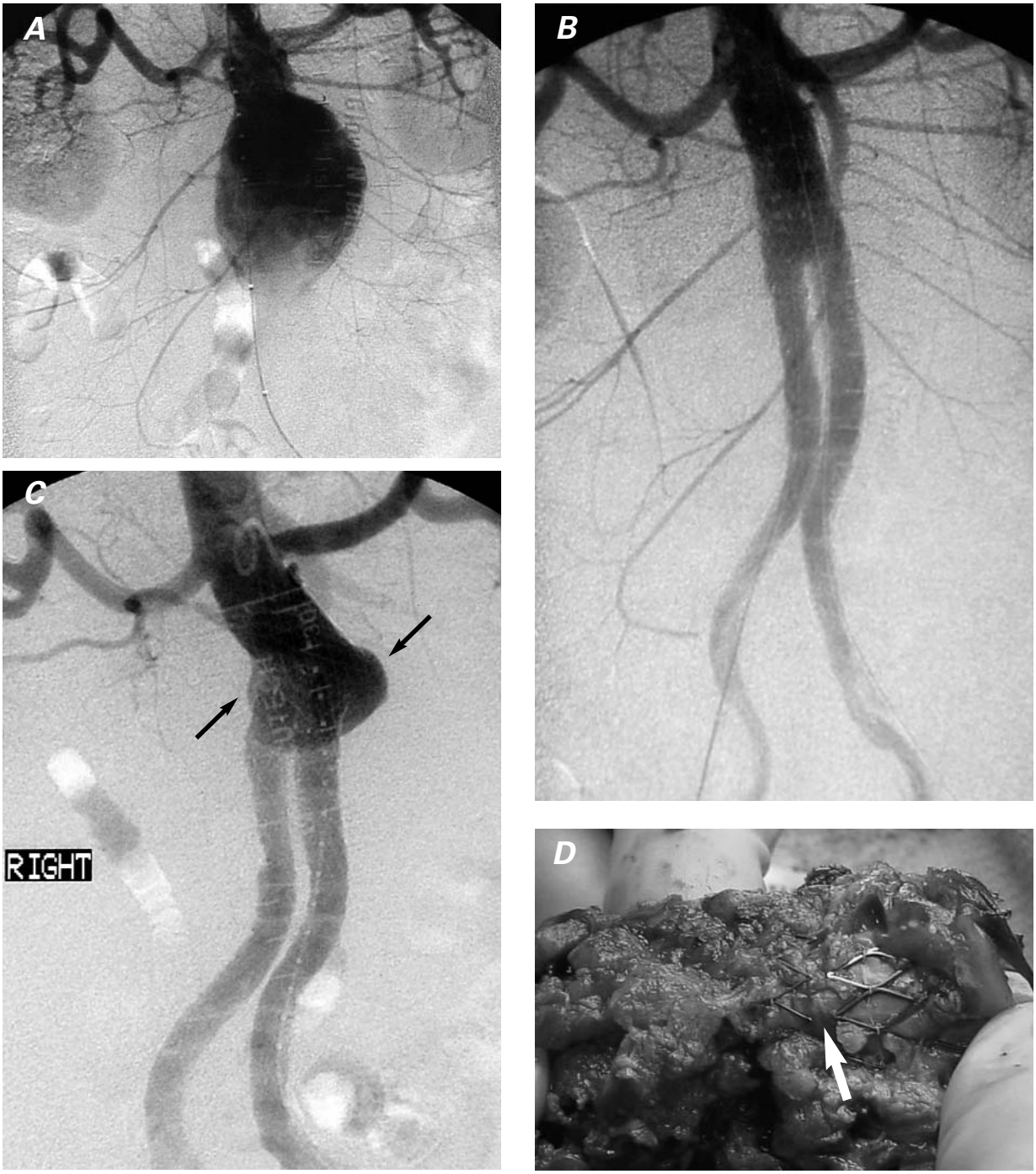

Fig. 5 *Patient 4.* ***A****) Abdominal angiogram before insertion of the AneuRx stent graft reveals the presence of a large, infrarenal AAA.* ***B****) Abdominal angiogram after deployment of the AneuRx stent graft reveals no evidence of endoleak.* ***C****) Abdominal angiography after 2 years shows a large endoleak in the proximal portion of the stent graft (arrows).* ***D****) Gross examination of the explanted stent graft reveals suture breakage.*

ment and kinking of stent grafts. This in turn has been implicated in stent graft distortion and modular separation, leading to endoleaks and graft failure.[2,8-10] It is likely that the impact of blunt mechanical trauma (as experienced by Patient 3) or the repetitive mechanical stress of vigorous rowing movements (as in Patient 4) easily disrupted a device already strained by the intrinsic stresses of aortic and aneurysmal remodeling.

Although we have presented the cases of 4 patients who developed late complications after the placement of AneuRx stent grafts, this problem has been de-

TABLE II. Characteristics of Patients with Endoleaks after Mechanical Trauma

Age/ Sex	Type of AneuRx Graft (mm)	Time to Trauma from Procedure	Trauma Type	Leak Type	Location	Treatment	Long-Term Outcome
78/M	26×165 bifurcated, 15×115 limb	3 weeks	Traffic accident	III	Right iliac	Failed cuff/ surgical repair	Alive and well
72/M	24×165 bifurcated, 14×115 limb	18 months	Syncope/ fall	I	Right iliac	Coil embolization/14×85 limb	Alive and well
87/M	28×165 bifurcated, 16×115 limb	20 months	Traffic accident	III	Limb bifurcation	Surgical repair	Dead
58/M	26×165 bifurcated, 16×115 limb, 26×375 cuff	24 months	Vigorous exercise	III	Aortic cuff & main component	Surgical repair	Alive and well

scribed with other stent grafts, as well. Several manufacturers have suspended production and sale of their devices (such as Corvita and Vanguard [Boston Scientific Corp.]) because of late stent graft failure. The failure of the Vanguard stent graft,[11] as determined on long-term follow-up, has been attributed to suture breakage and nitinol ring migration, which disrupted the integrity of the endograft.

Clinical Implications

What should the recommendations be for long-term care and follow-up of patients who undergo aortic stent graft placement for AAAs? First, it should be noted that this report is preliminary and observational and cannot be a source of firm recommendations. However, we suggest that physicians, when taking care of patients who have developed late Type I or III endoleaks with suspicion of graft disruption, should take a detailed history to investigate the role of any previous trauma or mechanical insult that may have occurred. The severity of trauma necessary to cause such problems is still unknown. Three of our 4 patients had trauma severe enough to require hospital admission or an emergency room visit. Therefore, it is less likely that trivial injury or mechanical stress sustained during normal activities is dangerous. Patients with modular stent grafts should probably be advised against unaccustomed and strenuous activities. These are activities that would be discouraged even after conventional repair, because they increase the blood pressure and shear forces on the graft and the native aorta alike. This warning, however, should not be construed as a prohibition of routine physical activity and exercise, which should be encouraged.

Regular 6-month follow-up visits and CT scans for several years are advisable (until the natural history of the procedure is clear), because such follow-up should detect any late complications before they become fatal. As in 3 of the 4 patients described here, most cases involve late complications that can easily be identified before they lead to death.

We would also like to point out that 2 of our 4 patients (Patients 1 and 2) were on chronic warfarin therapy, and both of these patients developed Type III endoleaks and pseudoaneurysms. Data concerning the effects of anticoagulation on the incidence of endoleaks and other complications after endovascular AAA repair are scarce. A recent study[12] found no increase in the incidence of Type I or II endoleaks in patients on chronic warfarin therapy, although there was a decrease in the likelihood of spontaneous closure of Type II endoleaks and that of aneurysm shrinkage. It is possible that warfarin therapy might worsen the effects of trauma and result in the perpetuation of endoleaks and pseudoaneurysms.

In summary, external mechanical trauma may be one of the causes of late AneuRx graft failure. Moreover, the insult can be many months in the past and may have gone unnoticed. However, if good long-term clinical and radiologic follow-up is performed, these complications can be identified and corrected so that they do not become fatal.

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